This filled application form is intended to serve as an example source of information to help applicants fill in their Forms C1 with the necessary details. Please note that the details given here are only indicative and the specific details needed may vary from project to project. All applicants are therefore required to incorporate text that is specific and relevant to their own projects. Technical details, accuracy of the information, etc. is the sole responsibility of the applicant.

Form C1 - INFORMATION TO RCGM TO CARRY OUT RESEARCH AND DEVELOPMENT INVOLVING HAZARDOUS MICROORGANISMS (HMOs), GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR HEALTHCARE AND INDUSTRIAL USE

Posting date: May 08, 2026

1. Applicants Details:

Name of the Applicants:	First name Last name
Designation:	Associate Professor
Name of Organization:	BITS Pilani, Hyderabad Campus
Address:	Bxxx, BITS Pilani-Hyderabad Campus Jawahar Nagar, Kapra Mandal
State / UT:	TELANGANA
District:	Medchal - Malkajgiri District
Village / Town / City:	Hyderabad
Pin Code:	500078
Office Phone Number:	+91-40-66303xxx
Mobile No:	xxxxx xxxxx
Email:	yourname@hyderabad.bits-pilani.ac.in

Co-applicants Details:

Name of the Applicant:	
Designation:	
Name of Organization:	
Address:	
State / UT:	
District:	
Village / Town / City:	
Pin Code:	
Office Phone Number:	
Mobile No:	
Email:	

Include more co-applicants if needed.

2. Application for:

IBSC approval to carry out R&D project titled "**Evaluation of the role of TGF-ß regulated long-non-coding RNAs (lncRNAs) as therapeutic targets in a mouse model**".

3. Product Code

CLB (This code will be generated by you while submitting to IBKP from the dropdown options)

4. Status of the Project:

NEW

5. Proposed work objective(s):

a) Cloning and overexpression studies of TGF-ß regulated lncRNA genes: *SNHG15, LINC01518, RP13-463N16.6, RP11-7F17.7, LASTR, LINC01629*, in human oral cancer cells FaDu, Scc-9, Cal 27 and SCC-25.

b) Generate stable oral cancer cell lines using lentiviral vectors targeting *LASTR* and *LINC01629* for i*n vivo* (mouse) studies on tumor growth.

6. Proposed work plan

6.1: Summary of the proposed work plan utilizing HMOs, GMOs/LMOs and product(s) thereof:

LncRNA genes will be cloned into pcDNA3.1(+) and pmirGLO vectors for transient transfections *in vitro* (using oral cancer cells) and carry out overexpression studies, cell proliferation assays, invasion assays, western blotting, luciferase reporter assays, qRT-PCR, etc.
shRNAs against *LASTR* and *LINC01629* will be cloned in lentiviral vectors (pLKO.1-TRC, pMDLg/pRRE, pMD2.G and pRSV-Rev) to obtain the viral particles using HEK293 cells for transduction into the cancer cells followed by puromycin selection to obtain stable cell lines. These cell lines will be used for *in vivo* experiments. to assess tumor growth in the nude mice.

6.2: Category(ies) [Biosafety level(s)] of experiments to be performed:
Recombinant DNA work and bacterial transformations, etc.: BSL-1
Cell culture experiments: BSL-2.
Animal experiments: ABSL-2

6.3: Level of containment and facilities appropriate for the proposed work:
BSL-1, BSL-2, ABSL-2

6.4 Location(s) at which research work would be performed and details of contact person(s):
Recombinant DNA and cell culture experiments will be done in B310, Department of Biological Sciences, BITS Pilani, Hyderabad Campus. This location has dedicated BSL-1 and BSL-2 facilities.
Animal studies will be conducted in the ABSL-2 facility in the Central Animal Facility (Room no. B001), BITS-Pilani, Hyderabad Campus, Regn No. 1912/PO/REBi/S/16/CCSEA.

6.5: Level of containment and facilities existing at above location(s):
BSL-1, BSL-2 and ABSL-2

7. Description of the HMOs, GMOs/LMOs and product(s) thereof proposed to be employed in the research proposal

7.1: Taxonomy of host(s) or the host(s) carrying the vector(s)/target gene(s):
E.coli DH5α & *Stbl3*: Phylum: Proteobacteria, Class: Gammaproteobacteria, Order: Enterobacterales
Cell lines: *Homo sapiens* Phylum: Chordata, Class: Mammalia, Order: Primates.

7.2: Morphology & Physiology:
E. coli strains are Gram-negative, facultative anaerobic organisms with a normal doubling time of 20 min.
Fadu, Scc25, Cal27 and Scc9 are polygonal adherent cells. Fadu, Scc25 and Cal27 have doubling time of 36 hours whereas Scc9 divides every 20 hours.

7.3: Belonging to Risk Group(s)/ Risk Category(ies) before genetic modification, if any
E. coli: RG-1.
Oral cancer cells: RG-2.

7.4: Belonging to Risk Group(s)/ Risk Category(ies) after genetic modification, if any
DH5α and *Stbl3* after transformation will belong to RG-1. The cancer cells after transient transfections and stable transductions belong to RG-2 after genetic modifications.

7.5:History of use :
E. coli strains to be used are widely used for subcloning experiments and isolation and maintenance of recombinant plasmid clones (Ref. i). They have a long history of safe use in BSL-1 labs.
The cancer cell lines proposed here are routinely used to study oral cancer associated processes (Refs. ii-v).

7.6: Anticipated new characters in GMOs/LMOs and product(s) thereof and expected difference as compared to conventional counterparts:
After transformation, both *DH5α*, *Stbl3* will become ampicillin-resistant, but no other morphological changes are expected.
After shRNA transfection, HEK293T cells will be discarded as per biosafety procedures.
After transient transfections the target genes are overexpressed.
The cancer cells after stable transduction will become puromycin-resistant and slow-growing. No other morphological changes are anticipated.

7.7 Anticipated functions of the product(s):
E. coli strain *Stbl3* cells will be used to propagate plasmids containing the gene of interest. The plasmids will

be isolated and, along with 3rd generation lentiviral vectors, will be used to transfect HEK293T cells. The viral particles will be used to transduce oral cancer cells to carry out gene knockdown studies *in vitro* and in nude mice.

7.8: Proposed fate of the HMOs, GMOs/LMOs and product(s) there of:
The stably transduced GMOs made will be cryopreserved for their utilization to carry out all the objectives of the project. The transiently transfected cells will be used for the cellular and molecular assays mentioned. The stably transfected cells will be used for all molecular assays and *in-vivo* studies proposed.

8. Details on:

8.1: Source of nucleic acid(s):
cDNA of human cells. shRNA against LASTR and LINC01629 designed using in-silico tools and chemically synthesized

8.2: Description of the target gene(s) and mode of action, if known:
LncRNA sSNHG15: Significantly upregulated and acts as molecular sponge for tumor-suppressive microRNAs
*LINC01518*L: Acting as an oncogene that promotes tumor progression by competing endogenous RNA (ceRNA)
RP13-463N16.6: Significantly dysregulated transcript in squamous cell carcinoma (SCC), function not known.
RP11-7F17.7: *):* Function not known

8.3: Vector map and Nucleic acid/ amino acid sequence(s) of the gene(s) incorporated into the host organism:
Details attached.

8.4: Description of the other gene(s) (such as marker, reporter gene, etc) inserted, deleted or modified, if any:
The recombinant DNA constructs provide resistance to ampicillin to *E. coli* cells and puromycin resistance to oral cancer cells.

8.5: Details of gene construct, if any
Please see the attachment.

8.6: Number of copies of the genes incorporated:
One copy per vector. Transformed *E.coli* contains ~100 copies for relaxed plasmids per cell (both lentiviral and expression constructs, ref. 1). Cancer cells, when transduced with lentiviral particles, 1-5 copies are estimated to be integrated according to literature (ref. vi). Whenever necessary, copy number will be determined by qPCR.

8.7: Whether the product(s) of target gene(s) have been implicated in toxic and/ or allergenic effect:
No.

9. Anticipated exchange of HMOs, GMOs/LMOs and product(s) thereof for research purpose, if any:
Not anticipated at present, will seek IBSC approval if there is a need for exchange.

9.1 What precautions will be taken to prevent any unintended dispersal of the HMOs, GMOs/LMOs and product(s) thereof?
Daily decontamination and regular monitoring of the decontamination processes, disposal of solid and plastic waste in disposal/biohazard bags as recommended and bleach treatment for disposal of liquid waste as per biosafety norms. All work will be carried out by personnel with appropriate protective clothing, gear etc. Training will be provided to handle biohazardous items and adherence to biosafety norms.

10. Proposed decontamination and disposal mechanisms:
All solid laboratory wastes will be placed in biohazard bags and decontaminated by autoclaving. Biohazard bags after autoclaving will be handed over by the department to M/s. GJ Multiclave India Pvt. Ltd., an institution-contracted third-party company which is responsible for safe disposal of the waste as per the noms of state and central governments. Used culture media and liquid waste will be treated with bleach in closed containers overnight. These containers will be emptied through the lab sinks.

11. Contingency plan and risk management measures in case of an unintentional release of the HMOs, GMOs/LMOs and product(s) thereof:

Any spill will be immediately disinfected by 70% ethanol or disinfectant/bleach as appropriate using paper towels which will be decontaminated by autoclaving after placing them in biohazard bags. Room fumigation will be used to disinfect cell culture rooms, if necessary. In emergency situations, we will inform the Chairman, IBSC and the biosafety officer.

12. Appropriate references and any other relevant information:

i. Sambrook, J., & Russell, D. W. (2001). Molecular Cloning: A Laboratory Manual (3rd ed.). Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.
ii. Rangan, S. R. (1972). A new human cell line (FaDu) from a hypopharyngeal carcinoma. Cancer, 29(1), 117–121.
iii. Rheinwald, J. G., & Beckett, M. A. (1981). Tumorigenic keratinocyte lines requiring anchorage and fibroblast support cultured from human squamous cell carcinomas. Cancer Research, 41(5), 1657–1663
iv. Rheinwald, J. G., & Beckett, M. A. (1981). Tumorigenic keratinocyte lines requiring anchorage and fibroblast support cultured from human squamous cell carcinomas. Cancer Research, 41(5), 1657–1663.
v. Gioanni, J., Fischel, J. L., Lambert, J. C., Demard, F., Mazeau, C., Zanghellini, E., Ettore, F., Chauvel, P., Lalanne, C. M., & Namer, M. (1988). Two new human tumor cell lines derived from squamous cell carcinomas of the tongue: Establishment, characterization and response to cytotoxic treatment. European Journal of Cancer & Clinical Oncology, 24(9), 1445–1455.
vi. Tolmachov, O., Tolmachova, T. & Al-Allaf F.A. (2011). Designing Lentiviral Gene Vectors. In: Viral Gene Therapy. Ed. Xu K. Intech Publishers, London, UK.

Remarks: Minutes of the Meeting and details of the vector maps are attached.

13. Confidential information :
No

14. Collaboration(s)-National :
No

15. Collaboration(s)-International :
No.

16. Whether the HMOs, GMOs/LMOs and product(s) thereof under consideration, have been deliberated earlier by the RCGM? If so, provide relevant 'Unique Application Code (UAC)' assigned for each of those deliberations: No

Sr.No.	Unique Application Code(UAC)

17. Declaration by the Applicant

- I declare and agree to comply with all the provisions mentioned in the regulations and Guidelines on Biosafety of recombinant DNA Research and Biocontainment,2017 and Guidelines & Handbook for Institutional Biosafety Committee(IBSC),2011 and other applicable Guidelines, as modified time to time by the Goverment of India.
- I would ensure that all investigators/ researchers and staff working in the area of HMOs, recombinant DNA, GMOs/LMOs and product(s) thereof understand and follow the aforesaid biosafety guidelines.
- I assure that adequate training would be conducted to create awareness about compliance requirements while working with biorisk inherent microorganisms and/ or recombinant organisms.
- The HMOs, GMOs/LMOs and product (s) thereof (transferred material), if any, will be utilized for RCGM approved purpose(s) only.
- I also assure that deviations to the above provisions, if any; arising out of the experiments would be brought to the notice of the Chairman-IBSC and the Member Secretary-RCGM immediately.
- I am aware that making false or misleading statements may attract penalty under the Environment (Protection) Act, 1986.

Signature with stamp & date :
21-Nov-2025

Name : Vivek Sharma

Designation : Associate Professor

- To be signed in original by hand. (Electronic/ scanned signatures not acceptable)

18. Certified & Forwarded by the Chairman of the IBSC:

- I certify that the information contained in this form has been checked by the Institutional Biosafety Committee (IBSC) and found to be complete.
- I further certify that investigator(s), researcher(s) and staff intended to work with HMOs, GMOs/LMOs and product(s) thereof have adequate training and experience for the proposed dealings.
- The proposal set out above has been considered and approved by the IBSC in its meeting held on DD/MM/YYYY as the agenda item no. xx.x and is forwarded to RCGM for further necessary action. (Copy of the duly signed minutes of relevant meeting is enclosed).

Remarks: IBSC approval minutes attached

Name:

Chairman

Designation: **Signature with stamp & date**

- **To be signed in original by hand. (Electronic/ scanned signatures not acceptable)**

This filled Annexure is intended to serve as an example source of information to help applicants fill in the necessary details. Please note that the details given here are only indicative and the specific details needed may vary from project to project. All applicants are therefore required to incorporate text that is specific and relevant to their own projects. Technical details, accuracy of the information, etc. is the sole responsibility of the applicant.

Appendix/Annexure

NUCLEIC ACID SEQUENCE OF TARGET GENES

LASTER lncRNA sequence

>NC_000010.11:c5596118-5596011,c5595579-5594984 Homo sapiens chromosome 10, GRCh38.p14 Primary Assembly
GTCCATCCATCACTTGCAGAAAACAAAAGAGAGCAAGAGAGAAGACAGTGGGTGAAGTCCTGGTTCCAG
ACTCCCCTTTTTGCCGGGATATGATGGATCTGTCAGCTGGTGCCTAGAGTCCTAGAGAGCTAGAGATGGA
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LINC01629 lncRNA sequence

>NR_133913.1 Homo sapiens long intergenic non-protein coding RNA 1629 (LINC01629), long non-coding RNA
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TCACTTCATTTACCAACCCTGGAACCGCAGACCTCTGGGCTTCCTGGCTCTAGGAATGCAGTGCAAGACA
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GGGAAGGCCATGGAGCTGAGGAAGG

> Human LASTR shRNA sequence:

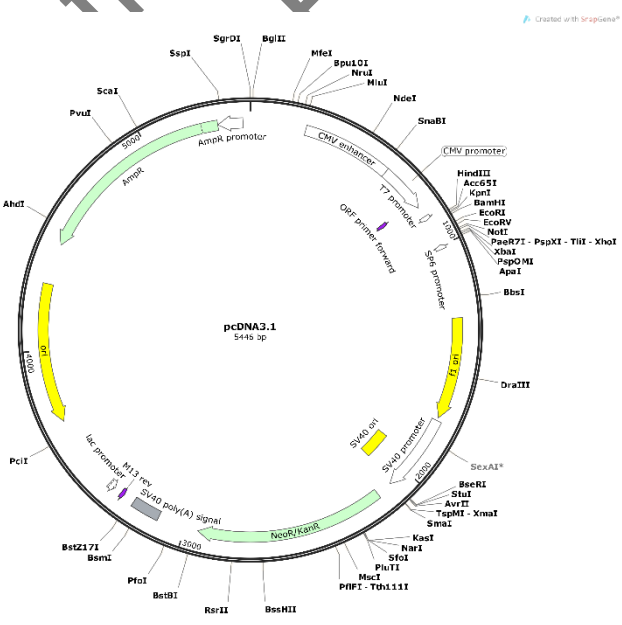
CCGGACAGGGTTAATGACTCAATTTCTCGAGAAATTGAGTCATTAACCCTGTTTTTTG

> Human LINC01629 shRNA sequence:

CCGGAGCCCTGGGGAGCCAGGGAGGCTCGAGCCTCCCTGGCTCCCCAGGGCTTTTTTG

Vector(s)

1. **pCDNA 3.1(+)**



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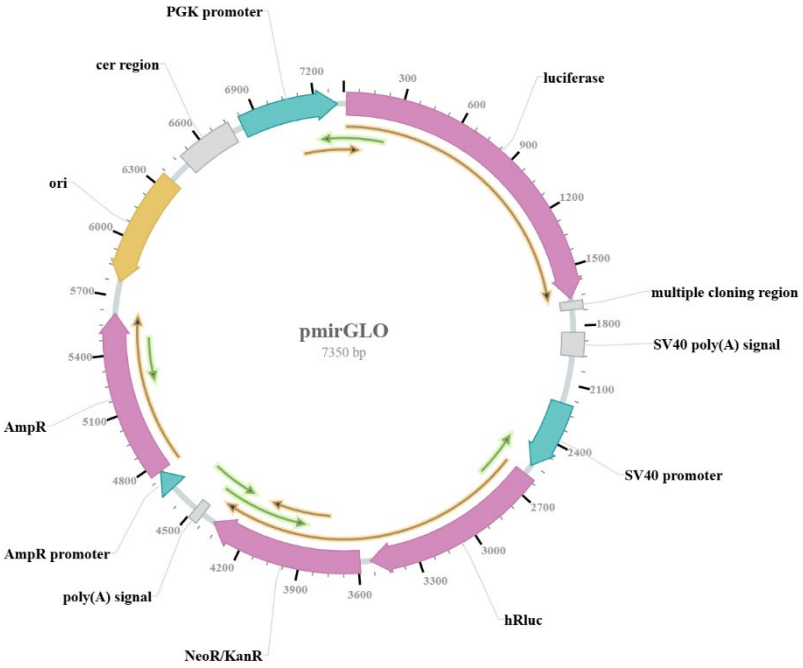
2. pmirGLO



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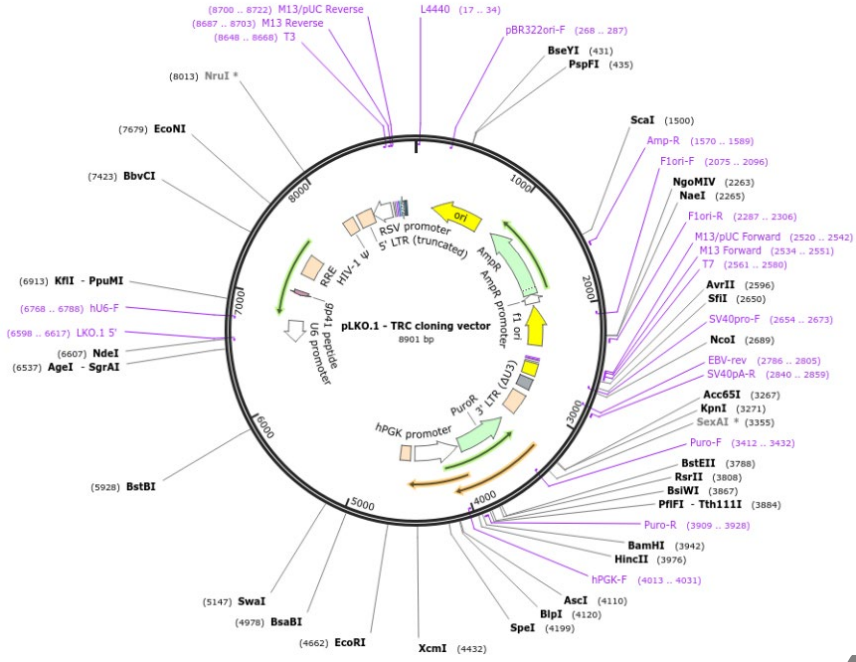

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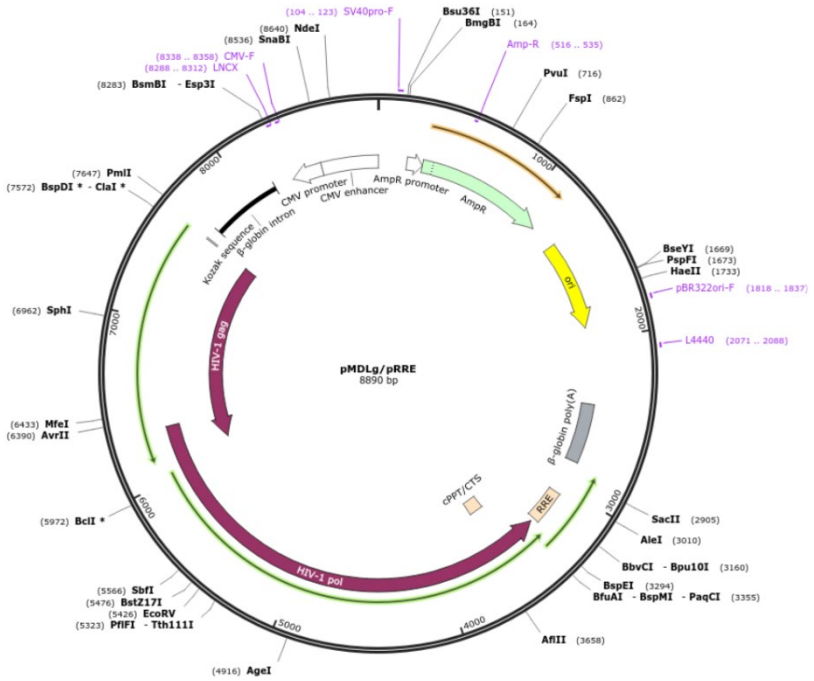

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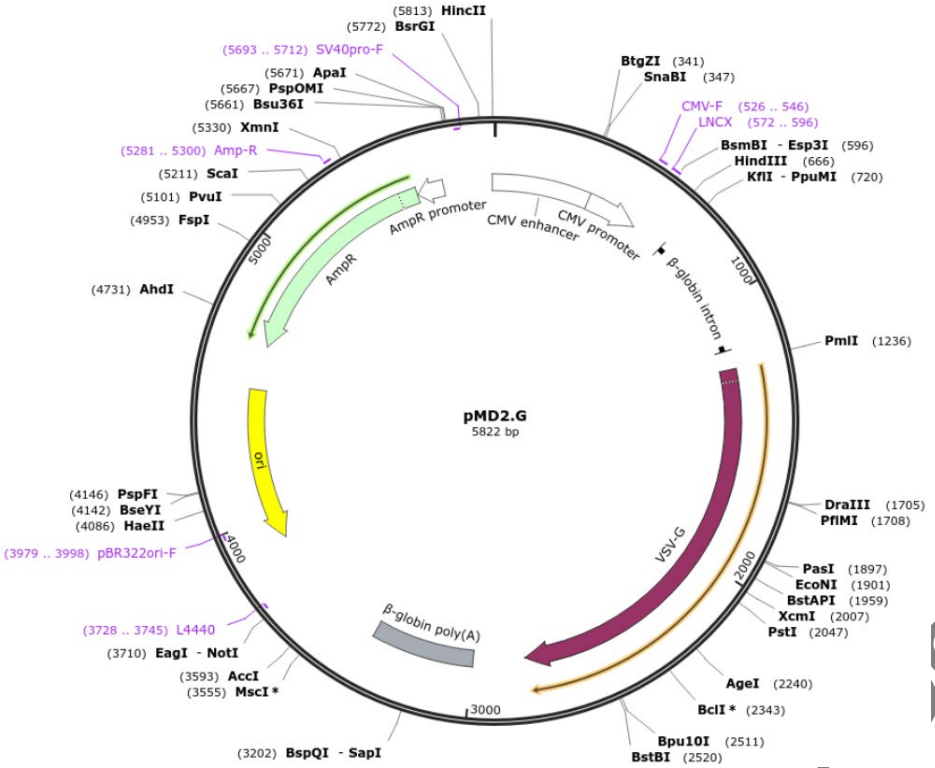

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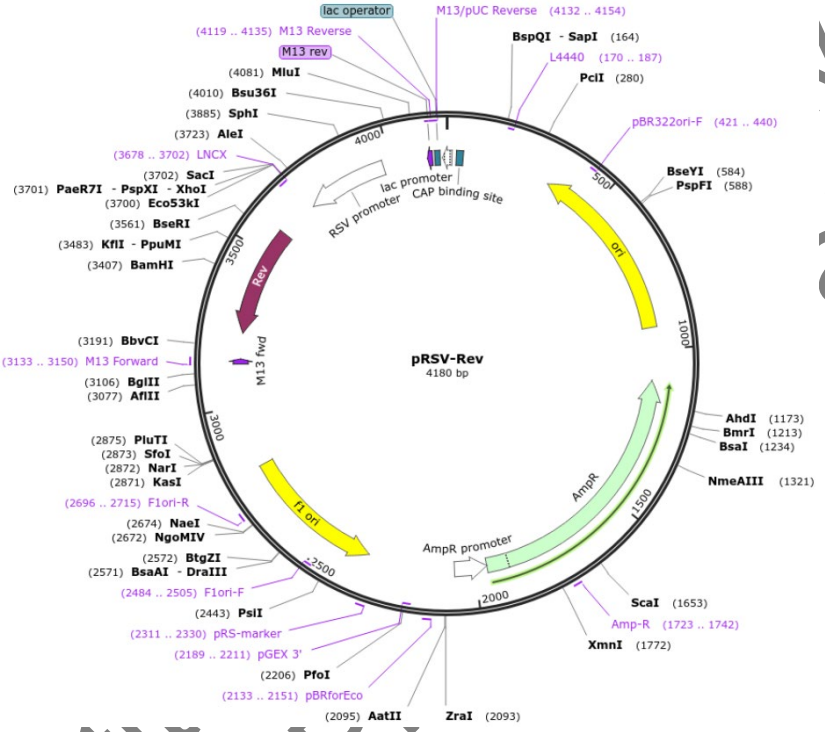

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